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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,573	09/30/2003	Michel H. Malek	036163-0101	9969

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EXAMINER

GANESAN, SUBA

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/675,573	Applicant(s) MALEK, MICHEL H. ✓	
	Examiner Suba Ganesan	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-28 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/04, 2/26/04/, 3/24/05, 4/26/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Adjustable Height Intervertebral Disc Prosthesis.

Claim Objections

2. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26-28 are rejected under 35 USC 112, 2nd paragraph for lack of sufficient antecedent basis. Claim 26 and its dependent claims 27 and 28 recite the limitation "the threaded rod" in Claim 26, line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3738

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Bryan et al. (U.S. Pat. No. 7,025,787).

Bryan discloses upper and lower members (104 and 106) defining arcuate surfaces surrounding a central member (108) capable of articulating along surface (132). In accordance with the definition of "disposed on" provided in the specification, the 'cup' is defined by the surface of the upper and lower members ('baseplates'). A centering post (128) provides a vertically adjustable support to the upper and lower members. The centering post (128) is a 'threaded stem' screwed into a 'tapped bore' on the upper and lower members.

Bryan further discloses that articulating surface (132) may be spherical or elliptical.

Bryan further discloses a posteriorly offset center of concavity (see figure 8B).

7. Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrington (U.S. Pat. No. 5,893,889). Harrington discloses an intervertebral disc prosthesis with a base portion (49) with a concave surface (51) disposed thereon. The lower member (34) has a threaded post (45) with a spherical upper end (46). The

Art Unit: 3738

threaded post (45) is vertically screwed into the lower member (34). The concave surface (51) and the spherical upper end (46) fit to provide an articulating joint.

8. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Jackson (U.S. Pat. No. 6,454,807). Jackson discloses a fusion cage system (1) comprising a first leg (10) and a second leg (11). A tapped bore is defined by base (12). An insert (13) engages the threaded bore of the base (12). The first leg (10) and second leg (11) comprise the tapped bore of base (12).

9. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Fleischmann (U.S. Pat. No. 6,375,682). Fleischmann discloses a spinal prosthetic adjustable in situ with rotatable bellows (26) that simulate one or more degrees of motion of a natural intervertebral disc.

10. Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Daher (U.S. Pat. No. 4,657,550). Daher discloses a connecting piece (5) (a 'base') with a buttressing means (8,9) (a superior and inferior 'vertically adjustable support') adjustably mounted onto the base using a threaded connection, with a tenon (a first and second 'intervertebral disc prosthesis') (14,15) mounted onto the buttressing means (8,9). The height of the tenon (14,15) can be adjusted by rotating the buttressing means (8,9).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3738

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan as applied to claims 1-5 above, in view of Xavier et al. (U.S. Pat. No. 6,063,121).

Bryan discloses the invention substantially as claimed including concave baseplates (104 and 106), a disc insert (108), and a vertically adjustable support (128). However, Bryan does not have a plurality of cables between the first and second base plates. Xavier teaches the use of multiple limiting wires (94) for the purpose of limiting rotation between plate members. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bryan with limiting wires in order to limit rotation of the baseplates.

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan as applied to claims 1-5 above, in view of Gill et al. (U.S. Pat. No. 6,113,637).

Bryan discloses the invention substantially as claimed including concave baseplates (104 and 106), a disc insert (108), and a vertically adjustable support (128). However, Bryan does not have a flat strip running through the apex of concavity of the first and second concave surfaces. Gill teaches the use of a substantially flat portion (52) of a concave surface (24) for the purpose of guiding translational motion of the implant. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bryan with a substantially flat portion of a concave surface in order to guide translational motion.

Art Unit: 3738

14. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan as applied to claims 1-5 above, in view of Paponneau et al. (U.S. Application No. 10/433,769).

Bryan discloses the invention substantially as claimed including concave baseplates (104 and 106), a disc insert (108), and a vertically adjustable support (128). However, Bryan does not have a first and second notch on the cup and baseplate, respectively. Paponneau teaches the use of a stud (207) whose planar face (272)('tab') engages holes ('notches') between the base (203) and the intermediate element (201) for the purpose of connecting the two body members (the baseplate and the intermediate element) of the device (see figure 6). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bryan with matched notches and an engagement means in order to connect the cup to the baseplate.

15. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '807 as applied to claim 12 above, in view of Jackson (U.S. Pat. No. 6,685,742).

Jackson '807 discloses the invention substantially as claimed including distinct baseplates (first and second legs, 10 and 11) comprising a tapped bore (12) engaged by an insert (13). However, Jackson '807 does not disclose a joint disposed between the first and second baseplates, and further does not disclose a cup-knob joint disposed between the first and second baseplates. Jackson '742 teaches the use of a cylindrical pivot member (34) and a knuckle (60) disposed between the first and second legs (10

Art Unit: 3738

and 11) for the purpose of articulation. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jackson '807 with a cylindrical pivot member (34) and knuckle (60) in order to provide for articulation of the device.

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '807 as applied to claim 12 above, in view of Jackson '742 and further in view of Bryan.

Jackson '807 and Jackson '742 disclose the same as above. However, Jackson '807 in view of Jackson '742 does not disclose baseplates with cups disposed thereon and a convex surfaced disc insert disposed between the cups. Bryan teaches upper and lower members (104 and 106) defining arcuate surfaces surrounding a central member (108) for the purpose of articulating along two convex surfaces. Therefore it would have been obvious to one of ordinary skill in the art at the time of this invention to modify the ball and socket joint of Jackson '742 with the arcuate surfaces (104 and 106) and central member (108) as taught by Bryan in order to at least enable articulation along two convex surfaces.

17. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson, 807 as applied to claim 12 above, in view of Mashburn (U.S. Pat. No. 7,022,138).

Jackson '807 discloses the invention substantially as claimed including distinct baseplates (first and second legs, 10 and 11) comprising a tapped bore (12) engaged by an insert (13). However, Jackson '807 does not disclose an aperture on a threaded rod or a matching aperture on the baseplate. Mashburn teaches the use of a circumferential threadless aperture (23) on a threaded shaft (17). The circumferential

Art Unit: 3738

threadless aperture (23) matches a threaded aperture (37) on a sleeve (28) for the purpose of locking the threaded shaft (17) to the sleeve (28). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jackson '807 with an aperture (23) on a threaded shaft (17) in order to lock the shaft to the sleeve.

18. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '807 as applied to claim 12 above, in view of Cauthen (U.S. Pat. No. 6,019,792).

Jackson '807 discloses the invention substantially as claimed including distinct baseplates (first and second legs, 10 and 11) comprising a tapped bore (12) engaged by an insert (13). However, Jackson '807 does not disclose an aperture on a threaded rod that extends over a vertebra when the disc prosthesis assembly is in place in an intervertebral space. Cauthen teaches the use of an opening (32) on a threaded shaft of a fusion chamber (30). The opening (32) allows for an engagement means for the purpose of connecting the implant device to a vertebra (see figure 4b). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jackson '807 with an opening (32) on a threaded shaft (30) in order to connect the device to a vertebra.

19. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan as applied to claims 1-5 above, in view of Middleton (U.S. Pat. No. 6,296,664).

Bryan discloses the invention substantially as claimed including concave baseplates (104 and 106), a disc insert (108), and a vertically adjustable support (128).

Art Unit: 3738

However, Bryan does not have a plurality of compressible helical slits. Middleton teaches the use of a plurality of generally helical slits (122) for the purpose of adding flexibility to the exterior wall of the disc member. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bryan with a plurality of helical slits in order to add flexibility to the disc member.

Bryan discloses the invention substantially as claimed including concave baseplates (104 and 106), a disc insert (108), and a vertically adjustable support (128). However, Bryan does not have a plurality of compressible helical slits disposed in a substantially parallel relation. Middleton also teaches the use of a plurality of generally helical slits that are disposed in a substantially parallel relation (see figure 10) to provide more flexibility. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bryan with a plurality of parallel helical slits in order to make the disc member more flexible.

20. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daher in view of Bryan.

Daher discloses the invention substantially as claimed including a connecting piece (5) (a 'base') with a buttressing means (8,9) (a superior and inferior 'vertically adjustable support') adjustably mounted onto the base using a threaded connection, with a tenon (a first and second 'intervertebral disc prosthesis') (14,15) mounted onto the buttressing means (8,9). However, Daher does not disclose a disc insert capable of articulating with convex surfaced cups. Bryan discloses upper and lower members (104 and 106) defining arcuate surfaces surrounding a central member (108) capable of

Art Unit: 3738

articulating along surface (132) for the purpose of simulating the motion of a natural intervertebral disc. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tenon (14,15) of Daher with the arcuate surfaced upper and lower members (104,106) and central member (108) of Bryan in order to simulate the motion of a natural intervertebral disc.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Errico et al. (U.S. Pat. No. 7044970) disclosing a ball and socket spinal implant capable of articulation; Boehm et al. (U.S. Pat. No. 6730126) disclosing oppositely disposed baseplates, each with threading to engage a separate threaded rod; Sweeny (U.S. PG PUB No. 20050085910) disclosing a threaded adjustable height vertebral disc prosthesis; Cohen et al (U.S. PG PUB No. 20040153156) disclosing an adjustable vertebral prosthesis; Ralph et al. (U.S. Pat. No. 6764515) disclosing a slotted articulating insert and two baseplates; Graham (U.S. Pat. No. 5246458) disclosing a vertically adjustable ball and socket joint disc prosthesis; Hedman et al. (U.S. Pat. No. 4759769) disclosing a disc prosthesis with a spring as the mechanism for height adjustment; Schafer et al (U.S. Pat. No. 7056343) disclosing multiple vertically threaded components; Hirayama et al. (U.S. Pat. No. 4946378) disclosing cups adjustably mounted to baseplates; Huang (U.S. Pat. No. 6966931) disclosing arcuate baseplates surrounding a convex insert; Suddaby (U.S. Pat. No. 6395034) disclosing adjustable arcuate baseplates; and Bertagnoli (U.S. Pat. No. 5480442) disclosing multiple articulating surfaces.

Art Unit: 3738

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 8/14/2006

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in black ink, reading "Brian E. Pellegrino", written in a cursive style.